

REMARKS

Claims 1-12 were pending in the present application. By this Amendment, Applicant has amended claim 1 and canceled claims 10 and 12. The cancellation of subject matter is without prejudice to Applicant's right to present such subject matter in a future continuing application. The present amendment does not introduce any new matter and thus its entry is respectfully requested. Upon entry of the present amendment, claims 1-9, and 11, will be pending and under examination.

August 21, 2008 Office Action

Species Election Requirement Withdrawn

The Office Action indicates that the Examiner found Applicant's previously elected species free of the art, expanded the search to include claims 1-12 in their entirety, and withdrew the election requirement.

In response, Applicant acknowledges and appreciates the withdrawal of the species election requirement.

Information Disclosure Statement

The Office Action indicated that certain documents listed on Applicant's Information Disclosure Statement filed April 1, 2005 were not available to the Examiner and thus have not been considered. The Office Action stated that Applicant may submit the missing references

with the response to the Office Action and that no fee for such submission will be required.

In response, Applicants attach hereto copies of the four references the Examiner has indicated were missing. Applicants respectfully request that these references now be considered.

Claim Rejection Under 35 U.S.C. §112, first paragraph

Claims 10 and 12 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner's full rationale for the rejection is set forth at pages 3-7 of the Office Action.

In response, without conceding the correctness of the Examiner's position, but to expedite allowance of the application, Applicant has canceled claims 10 and 12 without prejudice, rendering the rejection moot. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 10 and 12 under 35 U.S.C. §112, first paragraph.

Claim Rejections Under 35 U.S.C. §112, second paragraph, and 35 U.S.C. §101

Claims 10 and 12 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite, and under 35 U.S.C. §101, as allegedly failing to set forth proper process steps. The Examiner's full rationales for the rejections are set forth at pages 7-8 of the Office Action.

In response, without conceding the correctness of the Examiner's positions, but to expedite allowance of the application, Applicant has canceled claims 10 and 12 without prejudice, rendering the rejections moot. Accordingly, Applicant respectfully requests

reconsideration and withdrawal of the rejections of claims 10 and 12 under 35 U.S.C. §112, second paragraph, and 35 U.S.C. §101.

Examiner's Rejections Under 35 U.S.C. §102(b)

Claims 1 and 7-12 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ashley (U.S. Pat. No. 5,855,910). According to the Examiner, "Ashley teaches Applicants' compound of formula I where in R^1 =diacylglycerol R^2 =choline . . . and R^3 = C_1 - C_{24} straight chain alkyl or alkenyl."

The Examiner further asserted that "Ashley teaches that these phospholipids can be obtained from the parent phosphoglyceride." The Examiner also stated that Ashley teaches a class of cationic phospholipids, and the synthesis thereof, that are capable of generating liposomes. According to the Examiner, the liposomes are taught as methods of treatment of diseases or ailments amenable to treatment with nucleic acids or oligonucleotides.

The Examiner also rejected claims 1 and 4 under 35 U.S.C. §102(b) as allegedly anticipated by Bruzik, et al. According to the Examiner, Bruzik teaches the synthesis of glycerophospholipids wherein R^1 =diacylglycerol, R^2 =glycerol, and R^3 = Me.

In response, without conceding the correctness of the Examiner's positions, but to expedite allowance of the present application, Applicant has amended claim 1 to recite ". . . and each of R^2 and R^3 is a residue independently selected from ethanolamine, N-methylethanolamine, propanolamine, choline, glycerol, oligoglycerols, glycoglycerols or serine . . ." The claims, as amended, are not anticipated by either reference cited by the Examiner and

thus, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b).

Allowable Subject Matter


The Examiner indicated that claims 2, 3, 5, and 6 were objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form.

In response, Applicant acknowledges and appreciates the indication of allowable subject matter.

In light of the amendments and remarks presented herein, Applicant believes all of the rejections set forth in the August 21, 2008 Office Action have been fully overcome and the claims are in condition for allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite such allowance.

Respectfully submitted,

February 23, 2009

By 
Patrick T. Skacel
Reg. No. 47,948
Attorney for Applicant
Rothwell, Figg, Ernst & Manbeck, p.c.
1425 K Street, N.W., Suite 800
Washington, D.C. 20005
Telephone No.: (202) 783-6040
Facsimile No.: (202) 783-6031

Attachments: Copies of four previously cited references

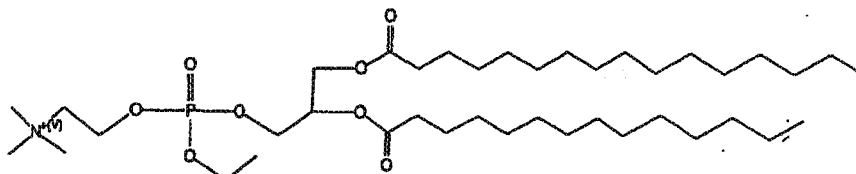
1582605_1.WPD

XP-002277994

cr

P.D. 08-03-2000

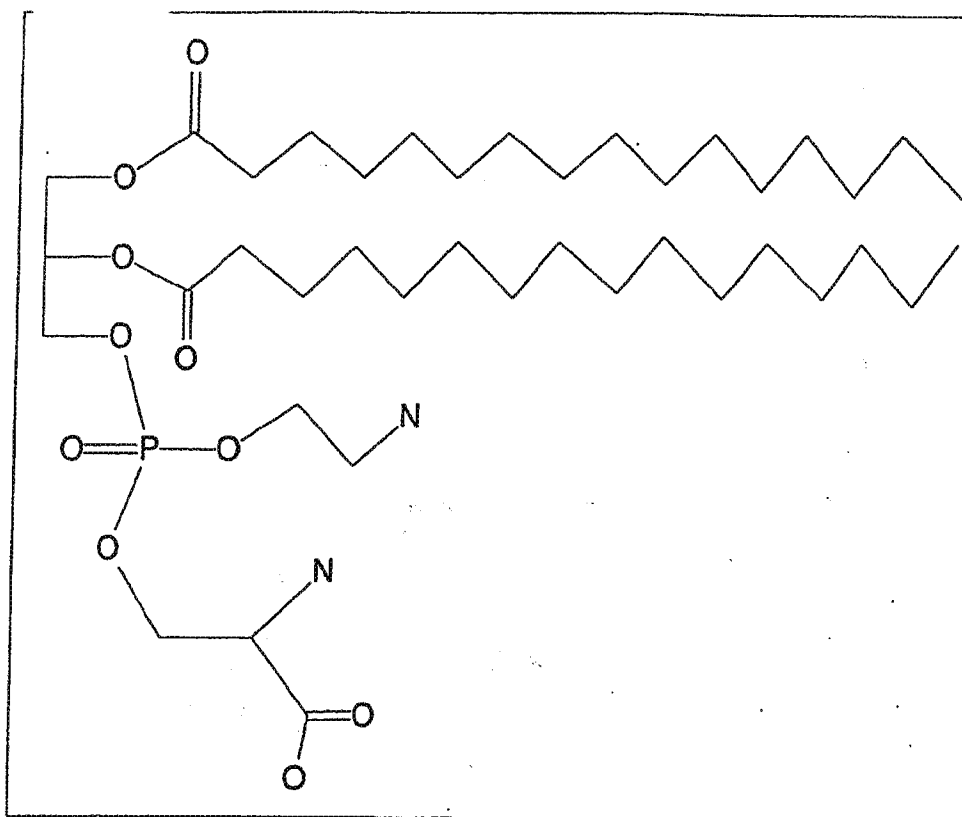
P. 1



Substance

Beilstein Registry Number	8384216
Chemical Name	ethyl palmityl myristyl phosphatidyl choline EPMPC
Autoname	{2-[ethoxy-(3-hexadecanoyloxy-2-tetradecanoyloxy-propoxy)-phosphoryloxy]-ethyl}-trimethyl-ammonium; chloride
Linear Structure Formula	$C_{40}H_{81}NO_8P^{(1+)}Cl^{(1-)}$
Molecular Formula	$C_{40}H_{81}NO_8P*Cl$
Molecular Weight	735.06, 35.45
Fragment BRN	8381555, 3587171
Lawson Number	3122, 2817, 1247, 1241, 636, 298
Compound Type	acyclic
Constitution ID	7118948
Tautomer ID	7903849
Entry Date	2000/03/08
Update Date	2000/03/08

XP-002277995



P.D. 05-00-00

P. 1-2

2

Substance

Beilstein Registry Number	6788943
Chemical Name	hexadecanoic acid 2-[(2-amino-2-carboxy-ethoxy)-(2-amino-ethoxy)-phosphoryloxy]-1-hexadecanoyloxymethyl-ethyl ester
Autoname	hexadecanoic acid 2-[(2-amino-2-carboxy-ethoxy)-(2-amino-ethoxy)-phosphoryloxy]-1-hexadecanoyloxymethyl-ethyl ester
Molecular Formula	C ₄₀ H ₇₈ N ₂ O ₁₀ P
Molecular Weight	779.05
Lawson Number	3549, 3122, 1241, 636
Compound Type	acyclic
Beilstein Reference	5-04
Entry Date	1994/11/08
Update Date	1994/12/21
Compound Disposition	<u>4084653 Alternate BRN</u>

Reaction

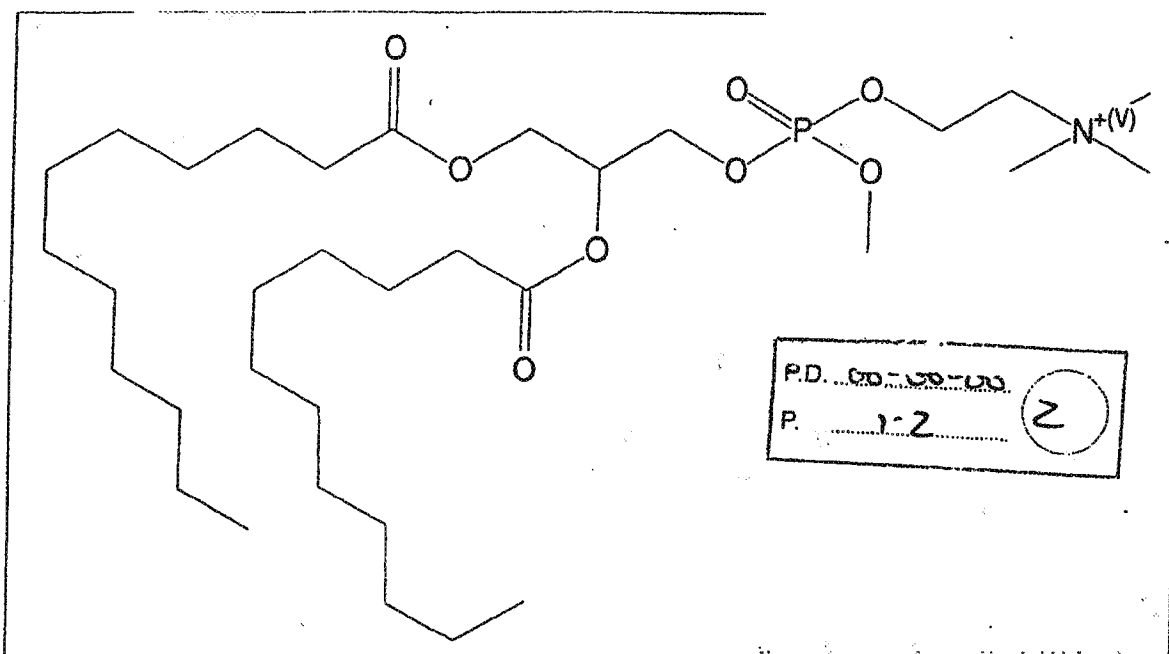
Reaction ID	<u>968101</u>
Reactant BRN	<u>1523304</u> hexadecanoic acid 2-[(2-benzyloxycarbonyl-2-benzyloxycarbonylamino-ethoxy)-[2-(1,3-dioxo-1,3-dihydro-isoindol-2-yl)-ethoxy]-phosphoryloxy]-1-hexadecanoyloxymethyl-ethyl ester
Product BRN	6788943 hexadecanoic acid 2-[(2-amino-2-carboxy-ethoxy)-(2-amino-ethoxy)-phosphoryloxy]-1-hexadecanoyloxymethyl-ethyl ester
No. of Reaction Details	1
Reaction Classification	Preparation

Copyright 1988-2001 Beilstein Institut zur Foerderung der Chemischen Wissenschaften. All rights reserved.

Other Conditions	(i) $\text{N}_2\text{H}_4 \cdot \text{H}_2\text{O}$, (ii) H_2 , Pd-C
Note 1	Multistep reaction
Ref. 1	<u>276200</u> ; Journal; Shvets, V.I. et al.; JOCYA9; J.Org.Chem.USSR (Engl.Transl.); EN; 5; 1969; 1978-1983; ZORKAE; Zh.Org.Khim.; RU; 5; 11; 1969; 2033-2039;

Infrared Spectra

Description	Bands
Ref. 1	<u>276200</u> ; Journal; Shvets, V.I. et al.; JOCYA9; J.Org.Chem.USSR (Engl.Transl.); EN; 5; 1969; 1978-1983; ZORKAE; Zh.Org.Khim.; RU; 5; 11; 1969; 2033-2039;



Substance

Beilstein Registry Number	7400057
Chemical Name	1,2-Dilaurylphosphatidylcholine methyl ester
Autoname	{2-[(2,3-bis-dodecanoyloxy-propoxy)-methoxy-phosphoryloxy]-ethyl}-trimethyl-ammonium
Linear Structure Formula	$C_{33}H_{67}NO_8P^{(1+)}$
Molecular Formula	$C_{33}H_{67}NO_8P$
Molecular Weight	636.87
Lawson Number	3122, 2817, 1237, 636, 289
Compound Type	acyclic
Constitution ID	6396749
Tautomer ID	7081128
Beilstein Reference	6-04
Entry Date	1996/04/26
Update Date	1997/02/03

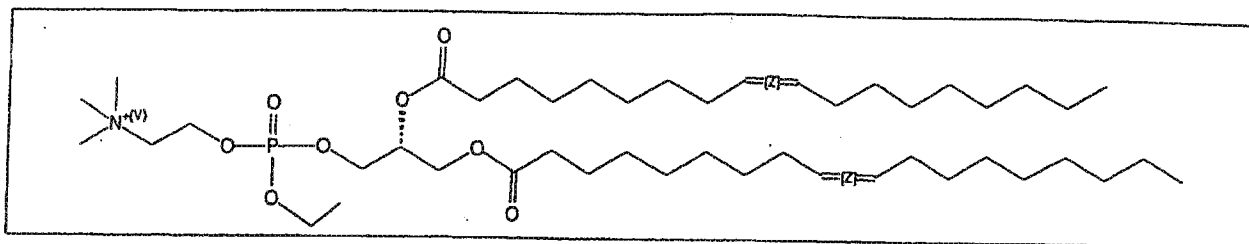
Reaction

Reaction ID	<u>4333536</u>
Reactant BRN	<u>102415</u> diazomethane
Product BRN	<u>4168394</u> 1,2-Dimyristoylglycerolphosphorylcholin 7400057 {2-[(2,3-bis-dodecanoyloxy-propoxy)-methoxy-phosphoryloxy]-ethyl}-trimethyl-ammonium
No. of Reaction Details	1
Reaction Classification	Preparation
Solvent	diethyl ether
Time	5 min
Other Conditions	Ambient temperature
Ref. 1	<u>6002834</u> ; Journal; Harvey, D. J.; JMSPFJ; J.Mass.Spectrom.; EN; 30; 9; 1995; 1333-

1346;

Mass Spectrum

Description	spectrum
Note 1	laser desorption
Ref. 1	<u>6002834</u> ; Journal; Harvey, D. J.; JMSPFJ; J.Mass.Spectrom.; EN; 30; 9; 1995; 1333-1346;



XP-002277997

Substance

Beilstein Registry Number	8468920
Chemical Name	1,2-dioleoyl-sn-glycero-3-ethylphosphocholine
Autoname	{2-[(2,3-bis-octadec-9-enoyloxy-propoxy)-ethoxy-phosphoryloxy]-ethyl}-trimethyl-ammonium
Linear Structure Formula	$C_{46}H_{89}NO_8P^{(1+)}$
Molecular Formula	$C_{46}H_{89}NO_8P$
Molecular Weight	815.18
Lawson Number	3122, 2817, 1371, 636, 298
Structure Keyword	Stereo compound
Compound Type	acyclic
Entry Date	2002/07/19
Update Date	2002/07/19

Pharmacological Data

Effect	drug interaction
Species or Test-System	COS-1 cells
Concentration	35 mmol/l
Kind of Dosing	title comp.-containing gene-delivery system (carrier) prepared as emulsion (E) or liposome (L)
Method	cells transfected with title comp.-containing carrier-DNA complex without/with fetal bovine serum (FBS) (DNA: Escherichia coli lacZ β-galactosidase, GAL> gene) in serum-free DMEM (1 h); GAL activity measured using photometric assay
Further Details	title comp. effect on transfection activity (TA) studied
Results	TA of DNA increased; without FBS: $TA(L) > TA(E)$; with FBS: $TA(E) > TA(L)$ (diagram)
Ref. 1	<u>6329889</u> ; Journal; Kim, Tae Woo; Chung, Hesson; Kwon, Ick Chan; Sung, Ha Chin; Jeong, Seo Young; PHREEB; Pharm.Res.; EN; 18; 1; 2001; 54 - 60;